



Multicenter Study Highlights Exceptional Surgical Efficiency of the Molteno3[®] Glaucoma Drainage Device

Fremont, California, 5 August 2020 – Nova Eye Medical Limited, a medical technology company committed to advanced ophthalmic treatment technologies and devices, is pleased to report the results of a retrospective, nonrandomized, noninferiority multicenter study which reinforces the surgical utility of the Molteno3[®] glaucoma drainage device, as compared to the Baerveldt[®] (Johnson & Johnson).

Published in *Ophthalmology*, the study by Dr. Arsham Sheybani and colleagues reported the surgical time of the Molteno3[®] SS-185 to be 15.7 minutes faster than the Baerveldt[®] BG-101-350.

According to Mr. Joe Bankovich, President of Nova Eye Medical, the Molteno3[®] is a game-changer for glaucoma surgeons, saving valuable time in the operating room while also delivering on clinical efficacy.

“The smaller plate of the Molteno3[®], which occupies approximately 40% less scleral real estate than the Baerveldt[®], makes it quicker to implant by an average of 15 minutes.* This optimizes the utilization of operating room resources.”

Clinical outcomes for the Molteno3[®] were also favorable. Despite the smaller surgical plate of the Molteno3[®], IOP reduction was within target range for the Molteno3[®] at the 24-month follow-up at 16.6 mmHg, compared to the Baerveldt[®] at 17.0 mmHg.

“Historically, there has been a perception that a larger plate is needed in order to achieve long-term IOP reduction. The study by Dr. Sheybani and colleagues validates an extensive body of clinical work that supports the clinical efficacy of the Molteno3[®],” said Mr. Bankovich.

“The Molteno3[®] has been designed with a smaller plate and unique geometry, including a patented Primary Drainage Area, to achieve the same efficacy outcomes as larger plates but with the benefits of a simplified and shorter surgical procedure.”

* Molteno3[®] SS-185 compared to the Baerveldt[®] BG-101-350.
Molteno3[®] SS-185 = 185 mm² plate size/ Baerveldt[®] BG-101-350 = 350 mm² plate size



The overall rates of failure were 27.5% for the Molteno3[®] compared to 45.5% for the Baerveldt[®]. Further, 100% of the Molteno3[®] glaucoma drainage devices were implanted by residents or fellows. According to Mr. Bankovich, this is testament to the simplified surgical technique of the Molteno3[®], in which the small plate size of 185 mm² eliminates the need to manipulate the extraocular muscles during implantation.

“The Molteno3[®] is the culmination of more than 50 years’ of research into glaucoma drainage surgery and represents one of the latest innovations in glaucoma implant technology. Despite offering enhanced surgical utility and optimized clinical outcomes, the Molteno3[®] has yet to find its rightful place at the top of the market. With the compelling results from this recent study, combined with our glaucoma-focused sales, marketing and clinical infrastructure, we look forward to growing the Molteno3[®] physician base in the USA and globally,” said Mr. Bankovich.

The publication of the study coincides with the completion of Nova Eye Medical’s acquisition of the Molteno3[®] ophthalmology assets from Molteno Ophthalmic Limited.

ABOUT THE STUDY

Retrospective, nonrandomized, multicenter comparative study comprising 117 eyes that underwent implantation of the Baerveldt[®] (n = 77) or the Molteno3[®] (n=40) glaucoma drainage device. Follow-up period was 24 months or greater.

Noninferiority study design provided robust evaluation of similarity between the devices, as opposed to nonsignificant P value from standard/superiority testing where nonsignificance may emerge from low statistical power due to small sample size and/or high variance versus a true lack of difference.

The primary outcome measure was the rate of failure, defined as IOP > 21 mmHg or a decrease <20% on two consecutive visits at 3-month follow-up, IOP </ 5 mmHg on two consecutive visits after 3-month follow-up, removal of device, loss of light perception vision, or reoperations for failure.

1. The overall rate of failure for the Baerveldt[®] was 45.5%
2. The overall rate of failure for the Molteno3[®] was 27.5%



Secondary outcome measures included Intraoperative time, mean post-op IOP, number of medications and VA.

Intraoperative Time:

1. The surgical time of the Molteno3[®] SS-185 as compared to the Baerveldt[®] BG-101-350 was 15.7 minutes faster.
2. The surgical time of the Molteno3[®] SS-185 as compared to the Baerveldt[®] BG-103-250 was 4.3 minutes faster.

Mean IOP:

1. With the Molteno3[®], IOP reduced from 22.8 mmHg at baseline to 16.6 mmHg.
2. With the Baerveldt[®], IOP reduced from 23.6 mmHg at baseline to 17.0 mmHg.

Mean Number of Medications:

1. With the Molteno3[®], the number of medications fell from 3.3 ± 0.8 at baseline to 2.0 ± 1.43 .
2. With the Baerveldt[®], the number of medications fell from 3.4 ± 1.0 at baseline to 2.1 ± 1.41 .

Access the paper:

[https://www.ophtalmologyglaucoma.org/article/S2589-4196\(19\)30304-7/abstract%22](https://www.ophtalmologyglaucoma.org/article/S2589-4196(19)30304-7/abstract%22)

Dixon MW, Moulin TA, Margolis MS, et al. Comparative Outcomes of the Molteno3 and Baerveldt Glaucoma Implants. Ophthalmol Glaucoma. 2020;3(1):40-50.

ABOUT THE MOLTENO3[®]

Supported by more than 50 years of scientific and clinical research and implanted in thousands of patients worldwide, the Molteno3[®] glaucoma drainage device has been clinically validated to deliver consistent, long-term reduction in intraocular pressure (IOP) in cases of severe or complex glaucoma. It has also been shown to offer the benefits of a more streamlined and efficient surgical procedure for improved practice efficiency.



ABOUT NOVA EYE MEDICAL

Nova Eye Medical Limited is a medical technology company that develops, manufactures and sells a portfolio of proprietary ophthalmic treatment technologies and devices. Used by eye surgeons in more than 100 countries globally, these technologies include iTrack™ minimally invasive glaucoma surgery (MIGS), a consumable surgical device that restores the eye's natural outflow pathway to lower pressure inside the eye and to eliminate patient reliance on anti-glaucoma medications for mild-moderate glaucoma. The Molteno3® glaucoma drainage device platform is designed to enhance surgical utility and optimize clinical outcomes for long-term IOP control in cases of severe or complex glaucoma. It also offers the benefit of a simplified and faster surgical profile. With its sales headquarters based in Fremont, California, Nova Eye Medical is supported by a global network of more than 50 distribution partners. Manufacturing facilities are located in Fremont, California and Dunedin, New Zealand.

For additional information about Nova Eye Medical and its technologies, please visit:
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